510(k) SUMMARY

Inion BioRestore™

K090177

FEB 20 2009

Manufacturer and submitter
Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND

Contact Person
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Establishment registration number
9710629

Trade name of the device
Inion BioRestore™
Inion BioRestore™ Sahara

Device classification and product code
Class II (Special controls)
Classification Panel: Orthopedic
Product Code: MQV
Common name: Resorbable bone void filler device
Regulation number: 888.3045

Predicate device
Inion BioRestore™ (K070998)

Conformance with performance standards
No applicable mandatory performance standards exist for this device.
Compliance to voluntary consensus standards is listed in the application.

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Inion BioRestore™

Device description and principles of operation

Inion BioRestore™ is an osteoconductive and osteostimulative bioactive bone graft device. In vivo tests have demonstrated more bone formation at each post-implantation timepoint and more total bone formation compared to other osteoconductive devices such as hydroxyapatite. In vitro cell culture tests with human adipose mesenchymal stem cells have demonstrated an osteostimulative effect, defined as the active stimulation of osteoblast proliferation and differentiation as evidenced by alkaline phosphatase activity. This stimulation has been attributed as being the result of the interaction between osteoblasts and the ionic dissolution products released from Inion BioRestore™ during its absorption. Clinical data on humans on rate and extent of bone formation observed in cell culture and animal models has not been established.

Bioactive materials are those materials that elicit a specific biological response at the interface of the material that results in the formation of a bond between the tissues and the material. Osteostimulation is a "...property of some bioactive materials to enhance, actively stimulate both the proliferation and differentiation of progenitor cells (e.g. mesenchymal stem cells)..."[1,2]

[1] Society for Biomaterials presentation, 24th Annual Meeting, 1998:511-518

[2] J Appl Biomat 1992, 3:123-129

Inion BioRestore™ system consists of different size cylinders, blocks and morsels made of degradable bioactive glass. When implanted, a kinetic modification of the surface occurs, resulting in the formation of a calcium phosphate layer that is essentially similar in composition and structure to the hydroxyapatite found in bone mineral. This apatite layer provides scaffolding onto which the patient's new bone will grow allowing complete repair of the defect. Based on pre-clinical testing, most of the material degrades in vivo in six months. The material is radiopaque. Inion BioRestore™ implants are intended for single use and are provided sterile to the user. They are completely synthetic and non-collagenous.

Indications for use

The Inion BioRestore™ implants are bone graft substitutes indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Inion BioRestore™ is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Substantial equivalence to marketed products

Based on the performance data and specifications presented, it can be concluded that the intended use, material composition and scientific technology, degradation properties, bioactive, osteoconductive and osteostimulative properties of the modified Inion BioRestore™ implants are substantially equivalent with the predicate device, when used in the indications for use described above, because the differences between modified Inion BioRestore™ implants and the predicate device do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Inion Oy
% Ms. Kati Marttinen
Regulatory Affairs Specialist
Lääkärinkatu 2, FIN-33520 Tampere
FINLAND

FEB 20 2009

Re: K090177
Trade/Device Name: Inion BioRestore™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: January 20, 2009
Received: January 23, 2009

Dear Mr. Marttinen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number:

Device Name: Inion BioRestore™

The **INION BIORESTORE™** implants are bone graft substitutes indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. **INION BIORESTORE™** is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restora...
and Neurological Devices

510(k) Number K090177